

**REMARKS**

By this amendment, claim 11 has been amended, claims 1-10 and 21-27 have been canceled, and claims 28-44 have been added. Upon entry of this amendment, claims 11-20 and 28-44 are pending, of which, claims 11, 28 and 38 are independent. No new matter has been added by this amendment.

Applicants' representative thanks Examiner Vrettakos for the courtesies extended during the February 22, 2006 personal interview, the details of which have been incorporated into the following remarks.

**Information Disclosure Statement**

It is requested that the Examiner provide a copy of the signed PTO-1449 filed January 3, 2005. Filed herewith is a supplemental Information Disclosure Statement. The Examiner is requested consider the documents cited therein and indicate such by signing, initialing, dating and returning a copy of the SB-08 to Applicants in the next communication.

**Rejection Under 35 U.S.C. 112, second paragraph**

Claim 13 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action states that the claims are narrative in form and replete with indefinite and functional or operable language; that the structure which goes to make up the device must be clearly and positively specified; that the claim neglects to positively identify new structure; and that instead the claim is a characterization of the device's placement during use as depicted in Applicant's Figure 2.

This rejection is respectfully traversed. The features of claim 13 are proper limitations in the context used and fairly convey the features to a person of ordinary skill in the pertinent art. (See M.P.E.P. 2173.05.) As called for in claim 13, the balloon and the wall of the artery delimit the volume of blood. Claim 13 meets the requirements of 35 U.S.C. 112, second paragraph. Withdrawal of the rejection is respectfully requested.

**Rejection Under 35 U.S.C. 102(e)**

Claims 11 and 12 have been rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,450,989 (Dubrul et.al.). The Office Action states that Dubrul discloses a hemostasis device (col. 10:54-60; figure 2) with an anchor balloon (4), a peripheral balloon (9), electrodes (col. 18:5-18), and a radiation (analogous but not necessarily anticipatory here to RF) power source (patented claim 5); that claim language regarding the effects of the electrodes (heating blood volume, coagulating blood, and closing a puncture) are toward the intended use of the device and carry no patentable weight in a device claim; and that sufficient anticipation is shown by the disclosure of electrodes in the prior art.

This rejection is respectfully traversed. The Dubrul patent is directed to a mechanical dilator or deployment mechanism. As discussed during the interview, the Dubrul patent is devoid of the combination of features of the hemostasis device as recited in at least claim 11. Claim 11 calls for at least one electrode to heat a volume of blood adjacent to the electrode and to cause coagulation of the blood and closure of the puncture. As recognized by the Examiner in the Office Action at page 4, "Dubrul neglects to expressly disclose blood volume delimiting". As appreciated by the Examiner in the interview, functional language in the last feature of claim 11 will be given patentable weight in future actions. (See February 22, 2006 Interview Summary record.) A non-narrowing amendment of claim 11 has been made to repeat this feature, in particular that the at least one balloon has "a configuration to delimit a volume of blood." Claim 11 defines patentable subject matter. At least for the reasons discussed with respect to claim 11, dependent claims 12 also defines patentable subject matter. Withdrawal of this rejection is respectfully requested.

**Rejections under 35 U.S.C. 103**

**Dependent Claims 13 and 20**

Claims 13 and 20 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul in view of U.S. Patent No. 5,928,266 (Kontos). The Office Action states that Dubrul refers to RF energy in col. 1:52-56; the Dubrul neglects to expressly disclose blood volume delimiting; that Kontos discloses a hemostasis device (analogous to Dubrul) comprising a pair of electrodes and an RF generator; that, therefore, at the time of the invention it would have been obvious to one of

ordinary skill in the art to modify Dubrul in view of Kontos by using Dubrul for hemostasis in a manner analogous to that in Kontos figure 9; and that the motivation to use Dubrul in this manner would be to simply choose a well-known method of hemostasis for the disclosed Dubrul device. The Office Action stated that delimiting blood volume is borderline intended use language; that this was addressed in the 112 rejection above; that, however, because Dubrul only makes reference to hemostasis once, Kontos is presented, which depicts in figure 9 a hemostasis device with an anchor balloon and sealing material; and that, further, Kontos depicts a pair of electrodes whereas Dubrul refers to "electrodes" but does not refer to multiple electrodes on a single embodiment.

This rejection is respectfully traversed. Kontos fails to satisfy the failings of Dubrul because Kontos also fails to disclose at least the features discussed above with respect to claim 11. Accordingly, dependent claims 13 and 20 are patentable at least for the reasons discussed above with respect to claim 11 and further for the additional features recited therein. Withdrawal of the rejection is respectfully requested.

#### **Dependent Claims 14-19**

Claims 14-19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul in view of Kontos and further in view of U.S. Patent No. 4,211,230 (Woltosz). The Office Action stated that Dubrul and Kontos neglect to disclose feedback control during hemostasis; that Woltosz discloses an electrosurgical device and a corresponding hemostatic method including radiofrequency electrodes, feedback control, and parameters making obvious the Applicant's claims; that, therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Dubrul in view of Kontos and further in view of Woltosz by integrating the Woltosz feedback controller as well as disclosed parameters, into the Dubrul/Kontos device and method, respectively; and that the motivation to use Woltosz in this manner would be to simply choose a well-known design expedient and hemostasis parameters for the speculated Dubrul/Kontos device.

This rejection is respectfully traversed at least for the reasons discussed above with respect to independent claim 11 and further for the additional features recited in dependent claims 14-19. Withdrawal of the rejection is respectfully requested.

**New Claims 28-44**

New claims 28-44 have also been included by this amendment. Independent claim 28 is directed to a hemostasis device where, among other things, the expandable member is of a configuration to delimit a blood coagulation volume by engagement of the expandable member against an outside of any artery wall and activation of the electrode causes blood disposed in the blood coagulation volume to coagulate causing closure of the puncture. Independent claim 38 is directed to a hemostasis device where, among other things, the expandable member has a configuration for defining a volume of blood adjacent a puncture in an artery wall and means for supplying an electric current to heat the volume of blood to cause coagulation of the blood and closure of the puncture. The prior art taken alone or in combination fails to disclose or suggest the inventions as claimed in claims 28 and 38 and the claims depending therefrom. Allowance of claims 28-44 is respectfully requested.

**Conclusion**

In view of the above amendments and foregoing remarks, applicant believes the pending application is in condition for allowance.

If a fee is due beyond those provided for in this filing please charge our Deposit Account No. 50-2228, under Order No. 023372.0110C1US from which the undersigned is authorized to draw.

Dated: February 24, 2006

Respectfully submitted,

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